REMARKS

The Amendment, filed in response to the Office Action, is believed to fully address all issues raised in the Office Action. Favorable reconsideration and allowance of the application are respectfully requested.

Disposition of Claims and Claim Amendments

As of the mailing of the Office Action, claims 1-7, 9-11 and 13-17 were pending. Claims 16-17 have been withdrawn and claims 1-7, 9-11 and 13-15 have been under examination and rejected.

In the current Amendment, claim 1 is amended in order to more clearly set forth the claimed subject matter. Amendment to claim 1 is supported by, for example, the disclosure at page 7, lines 3-7 and page 9, line 26 of the specification as filed. Claim 2 is amended to insert "the amount of" in front of the respective ingredients recited therein.

Claim 18 is newly added. New claim 18 is supported by claim 1 and the disclosure at page 7, lines 3-7 and page 9, line 26 of the specification as filed.

Upon entry of the amendment, claims 1-7, 9-11, and 13-18 will be pending in the application.

No new matter is introduced. Entry and consideration of the amendment are respectfully requested.

Response to Claim Rejections Under 35 USC § 103

1. Summary of Rejections

In the Office Action, claims 1, 3-7, 9-11 and 13-15 stand rejected under 35 U.S.C. 103(a) as assertedly being unpatentable over Gutierrez-Rocca et al. (US Patent No. 6524615, cited in the Office action mailed on 3/30/10) in view of Baichwal et al. (US Patent No. 5135757, cited in the Office action mailed on 3/30/10) as evidenced by Mosquera et al. (Int. J. Pharmaceutics, 1996, cited in the Office action mailed on 3/30/10).

In the Office Action, claim 2 is rejected under 35 U.S.C. 103(a) as assertedly being unpatentable over Gutierrez-Rocca et al. in view of Baichwal et al. as evidenced by Mosquera et al. and in further view of Serajuddin et al. (US Patent No. 5433951, cited in the Office action mailed on 3/30/10).

Gutierrez-Rocca is cited as disclosing a sustained or prolonged release pharmaceutical unit dosage form comprising a hard shell capsule and a formulation comprising (1) water insoluble medicament such as atorvastatin, simvastatin, lovastatin (all HMG-CoA reductase inhibitors); (2) a high melting fatty acid ester: (3) low viscosity oil (wherein 2 and 3 read on carrier); (4) a cellulosic polymer such as methocel E series and K series which read on gel hydration accelerator; (4) a non-ionic surfactant such as poloxamers and d-2-tocopheryl polyethylene glycol 1000 succinate (which read on solubilizer).

The Examiner recognizes that Gutierrez-Rocca does not teach the inclusion of the hydrophilic polymers such as sodium alginate, locust bean gum, xanthan gum and propylene glycol ester alginate.

Baichwal is cited as teaching a slow release granulation for use as a directly compressible pharmaceutical excipient, wherein the excipient comprises a heteropolysaccharide or a gum having similar properties and a polysaccharide material capable of crosslinking. Baichwai is also cited as teaching that other hydrophilic material can be added such as alginates, hydroxypropymethyl cellulose and the like (column 6, lines 20-28).

The Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Gutierrez-Rocca et al. and Baichwal et al. and utilize a combination of heteropolysaccharides and polysaccharides in the sustained release composition of Gutierrez-Rocca et al to reach claim 1.

The Examiner also contends that the features of dependent claims 3-7, 9-11, and 13-15 are taught in Gutierrez-Rocca and/or Baichwai.

With regard to claim 2, the Examiner recognizes that Gutierrez-Rocca does not teach amounts that are suitable. Serajuddin is cited as teaching that, in sustained release formulations, antioxidants for fatty acid glycerides such as ascorbic acid or butylated hydroxy toluene can be present in an amount within the range from about 0.005 to about 2%, preferably from about 0.01 to about 1% (column 3, lines 51-27).

In the Office Action, Claims 1, 3-4, 7, 9-11 and 13-15 are rejected under 35 U.S.C. 103(a) as assertedly being unpatentable over Louie-Helm et al. (USPGPUB No. 20030091630, cited in the Office action mailed on 3/30/10) in view of Baichwal et al.

Louie-Helm is cited as teaching a formulation of an erodible gastric retentive oral dosage form which contains bioerodible polymers which determine the rate at which the polymer matrix erodes include cellulosic polymers such as hydroxypropyl methylcellulose with

viscosity in the rage of about 50 to 110,000 (paragraph 0059, 0063 and 0082) and polysaccharide gums such as xanthan gum (paragraph 0079 and 0084) as well as natural polymer s such as alginates (paragraph 0086).

The Examiner states that Louie-Helm does not exemplify formulations comprising sodium alginate, xanthan gum and locust bean gum or hydroxypropyl methylcellulose, propylene glycol ester alginate and the other polymers. The Examiner cites Baichwai as teaching compressible sustained release solid dosage forms containing a slow release granulation for use as a directly compressible pharmaceutical excipient, wherein the excipient includes a heteropolysaccharide or a gum having similar properties and a polysaccharide material capable of crosslinking.

2. Applicant's Responses

Applicant respectfully submits that currently amended claim 1 is patentable over Gutierrez-Rocca and Louie-Helm, either alone or combinations with Baichwai, Mosquera, and Serajuddin, for the following reasons.

Currently amended claim 1 recites (emphasis added):

> A sustained release formulation for oral administration of an HMG-CoA reductase inhibitor comprising:
>
> **a spray-dried solid dispersant in the form of particles having a particle size ranging from 5 to 200μm,** wherein the solid dispersant contains the HMG-CoA reductase inhibitor, a solubilizing agent, and a stabilizing agent;
>
> a mixture of sodium alginate and xanthan gum as a sustained release composite carrier; and
>
> a mixture of propylene glycol ester alginate and hydroxypropyl methyl cellulose as a gel hydration accelerator.

None of the cited references teach the feature that the HMG-CoA reducatse inhibitor is in a spray-dried solid dispersant which is in the form of particles having a particle size ranging 5-200 μm, together with a solubilizing agent and a stabilizing agent.

Gutierrez-Rocca teaches a sustained/prolonged release pharmaceutical dosage form is disclosed. The form comprises a hard shell capsule and a formulation comprising (a) a water insoluble medicament, (b) a high melting fatty ester, (c) a low viscosity oil, (d) a cellulosic polymer, and (e) a non-ionic surfactant. These ingredients (a)-(e) are prepared and present as a single mixture, and incorporated into the hard shell capsule. In particular, Gutierrez-Rocca states at column 7, lines 5-13:

> The sustained/prolonged release pharmaceutical unit dosage forms are prepared by fluidizing matrix carrier material or components, e.g. a high melting fatty acid ester, an oil, a cellulosic polymer or a mixture of the foregoing, to provide a formulation, to which is added the medicament which dissolves therein, which is then filled into a hard shell capsule, while in the fluid state, and, generally, allowed to solidify in the capsule.

Louie-Helm also is completely silent regarding a spray-dried solid dispersion which is in the form of particles having a particle size ranging 5-200 μm, wherein the solid dispersant contains the HMG-CoA reductase inhibitor, a solubilizing agent, and a stabilizing agent.

None of the secondary references, including Baichwai, Mosquera, and Serajuddin, cures the above defects. Therefore, the cited references, either singly or in combinations, fail to teach all and every limitation of currently amended claim 1.

Furthermore, as previously shown in the Rule 132 Declaration submitted on August 2, 2010, the claimed product shows unexpectedly superior effects such as improved solubility,

bioavailability and stability, which are attributed by the features recited in claim 1 of the instant application. In addition, since the sustained release composite carrier has a high viscosity, a mixture containing the same, i.e., the dosage form of Gutierrez-Rocca, cannot be prepared by spray-drying, and, even if the spray-drying method is possible, the sustained release composite carrier cannot exhibit its proper ability in a spray-dried formulation.

Accordingly, currently amended claim 1 is patentable over the cited references, either alone or in combinations, and withdrawal of the rejections is respectfully requested.

Claim 18, which requires the spray dried dispersion consist of the recited ingredients, is also patentable over the cited references, at least for the same reasons of patentability of currently amended claim 1.

Dependent claims 2-7, 9-11, and 13-15 are also patentable at least for their dependency from amended claim 1.

Response to provisional Obviousness-type Double Patenting Rejection

On page 16 of the Office Action, claims 1, 3-7, 9-11 and 13-15 are provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 10650931 (Woo et al., PGPUB No. 20040081693) which has a common inventor with the instant application in view of Gutierrez-Rocca et al. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if published or patented. Applicant notes that the copending Application No. 10650931 was issued as patent No. 7,704,526, and submitted a Terminal Disclaimer on August 2, 2010.

In this regard, Applicant notes that the Examiner, on page 21 of the Office Action, acknowledges the filing of the Terminal Disclaimer submitted on August 2, 2010 with respect to the copending Application No. 10650931 (now patent No. 7,704,526) and withdraws the double patenting rejection.

Accordingly, it is respectfully requested that the Examiner includes an updated status of the provisional obviousness-type double patenting rejection in a next Action.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number **202-775-7588.**

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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